

### **REMARKS**

Favorable reconsideration of this application as presently amended is respectfully requested. Claims 1-24 are pending. In this Amendment, claims 1 - 24 are amended. Claim 25 is new. No new matter is added.

Support for the amendment to independent claims 1, 23 and 24 adding that the drag material is "malleable" is found at page 9, line 6 of the specification. The support for the addition of the term "deployable" to the foregoing independent claims is found at page 11, lines 26-28. The support for the addition of the protective sheath being deployable "from a packed position to an extended position" is found at page 11, lines 21 - 23, 26 - 28, page 24, line 5, and figure 7. The support for the "second portion of said malleable drag material being exterior of said deployable protective sheath" is found at page 10, lines 25 - 27 and figures 7 and 8.

The Examiner is thanked for indicating that claims 4-6, 10-22 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 12 and 23 are objected to because of informalities. Claim 12 has been amended to replace the trademark "Teflon" with the work polytetrafluoroethylene. The typographical misspelling in Claim 23 has been corrected.


### **35 U.S.C. §102 Rejections**

Claims 1, 2, 8, 9, 23 and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,946,440 to Hall. This rejection is respectfully traversed with respect to the claims as currently presented.

Claims 1, 23 and 24 as amended claim a device having a malleable drag material and a deployable sheath that extends from a packed position to an extended position.

The Hall device includes an outer tube 12 and a connected inner tube 16 that in turn carries a lumen 98 with a tip 70. As the inner tube 16 extends beyond the outer tube 12 and the lumen 98 extends beyond the inner tube 16. Although it is stated in the Hall patent that the elements are flexible, there must be some degree of rigidity in order to maintain shape and to permit the tubes to extend and retract. In accordance

with the instant invention and the Merriam Webster definition below, the Hall device would not function as intended if the elements were malleable.

Main Entry: **mal·lea·ble** 

**2 a** : capable of being altered or controlled by outside forces or influences **b** : having a capacity for adaptive change

The Examiner has referred to the outer tube 12 as a capsule; however this is not consistent with the teachings of the Hall patent. As seen in the Hall drawings and stated at Col. 7, lines 5-7, the Hall device is a series of telescoping tubes. A series of telescoping tubes does not meet the definition of a capsule, as set forth in the Encarta Dictionary definition wherein a capsule is defined as:

**1. pill or casing**

PHARMACOLOGY a pill consisting of a small cylindrical container made of a soluble substance such as gelatin, enclosing a dose of medicine or a nutritional supplement, or the container itself

Merriam Webster defines capsule as:

Main Entry: **cap·sule**

**3** : a shell usually of gelatin for packaging something (as a drug or vitamins); *also* : a usually medicinal or nutritional preparation for oral use consisting of the shell and its contents

Further, the device of Hall is not swallowed, but rather inserted into the cavity.

Claims 2, 8 and 9 depend directly or indirectly from claim 1, and, accordingly, include all of the patentable features of claim 1 as well as other patentable features. Therefore, claims 2, 8 and 9 are patentable over Hall for at least the reasons discussed above with respect to claim 1.

Claim 2 teaches the novel device of claim 1 as being used for the diagnosis of gastrointestinal pathogens. The diagnosis of gastrointestinal pathogens is not novel, however, the device used, as disclosed in claim 1, is novel and therefore its use is patentable.

Claim 8 teaches the use of a capsule to deliver the drag material and protective sheath. As stated heretofore, the Hall device does not use a capsule for delivery but rather uses a series of extendable tubes to lengthen the device as it is inserted into the cavity. Further, the Hall device does not have either a malleable drag material or a deployable protective sheath, both critical elements to the device taught in the pending application.

Claim 9 teaches that the deployable protective sheath goes from a packed position to an extended position through movement. The inner tube 16 of the Hall device does not start off in a packed position, but rather is retracted into and extended from, the outer tube 12. As the Hall inner tube 16 must slide within the outer tube 12, it is impossible for the elements to be manufactured from a material that is able to be packed in the manner of the instant invention.

Claim 23 has been amended to clarify that the deployable sheath extends from its packed position to its extended position to enclose a portion of the drag matter. As stated heretofore the inner tube 16 Hall device does not start in a packed position and then extend to enclose the drag material. Rather the Hall inner tube 16 is extended from the outer tube 12 and, through use of a lumen 98, the tip 70 is extended from or withdrawn into the inner tube 16. Neither the tip 70 nor the lumen 98 are malleable as that would make the Hall device inoperable.

Claim 24 has been amended to more clearly set forth the method of manufacturing the sampling device by stating that there are two portions to a malleable drag material, one portion which is enclosed in the a capsule and the second portion which extends from the exterior of the capsule.

In the Hall device the tip 70 is a small probe or swab and only extends from the inner tube. There are no teachings that the tip 70 is a malleable material and, as the inner tube 12 cannot truly be considered a capsule to be swallowed, the tip 70 cannot be considered to extend in any direction but from the distal end of the inner tube 12.

### **35 U.S.C. § 103(a) Rejections**

Claims 3 and 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall as applied to Claim 1 and further in view of U.S. Patent No. 5,425,377 to Callouette. This rejection is respectfully traversed with respect to the claims as currently presented.

Claims 3 and 7 depend directly or indirectly from claim 1, and, accordingly, include all of the patentable features of claim 1 as well as other patentable features. Therefore, claims 3 and 7 are patentable over Hall for at least the reasons discussed above with respect to claim 1.

Pending claim 3 relates to a malleable drag material of absorbent string, cotton, sampling cloth, wool, acrylic, nylon, plastic, chain links and finely woven metal or mixtures thereof. Applicant is not seeking patentability on the use of these materials, per se, but rather the incorporation of these materials into the novel testing device of claim 1.

In pending claim 7, the instant invention further adds a pH or urease indicator to the malleable drag material. Again, applicant is not attempting to patent either a pH nor a urease indicator, but rather the incorporation of these indicators into the novel device as set forth in Claim 1.

Claim 25 has been added. Support for claim 25 can be found in the specification at page 23 lines 15 - 37 through page 24, lines 1 - 15.

If the Examiner has any questions or concerns regarding the present response, the Examiner is invited to contact Sheldon Parker at 703-563-2041.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance, and favorable action is respectfully solicited.

Respectfully submitted,



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